

# EXHIBIT 2

Message

**From:** Lee, Anthony [Anthony.Lee1@fda.hhs.gov]  
**Sent:** 6/30/2022 3:54:30 PM

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]

So my best guess would be on the order of weeks. There's some new policy considerations being made at the moment which may set some precedents for the remanufacturing space moving forward. Given that, I think days would be very unlikely.

Regards,  
Anthony

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**Sent:** Wednesday, June 29, 2022 8:26 PM  
**To:** Lee, Anthony <Anthony.Lee1@fda.hhs.gov>  
**Subject:** Re: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Thanks for the quick reply Anthony.  
Do you have any indication on timing?  
Is days, weeks or longer?

Thanks again for your assistance.

Very Best Regards

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**From:** "Lee, Anthony" <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>  
**Date:** Wednesday, June 29, 2022 at 11:21 AM

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]

I appreciate your team's patience as the review continues to proceed internally. The biggest challenge, and the primary reason for the wait thus far, is that your company is performing remanufacturing which carries additional considerations that are not originally part of FDA premarket review. Additional review teams focused on remanufactured devices have been looking into this submission, and we are waiting on feedback as to how this review will move forward. As mentioned before, we still have no additional asks from you at the moment. We appreciate your patience thus far, and I will continue to reach out if we need anything further.

Best regards,  
Anthony

**Anthony Lee, PhD, MBA**

*Team Lead*

**Robotic Assisted Surgery Devices Team**

**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**

**Office of Product Evaluation and Quality | Center for Devices and Radiological Health**



Office: (240) 402-5935

E-mail: [Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)

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**Sent:** Tuesday, June 28, 2022 9:40 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Subject:** Re: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Good evening Anthony

With [REDACTED] being away on vacation, I wanted to make sure I was on top of any developments here. It has been 11 days since our last communication and I thought we were close to the "finish line".

Is there anything else you are requiring from our team here?

I will be managing the project while Rafal is away.

Please let me know.

Thanks  
[REDACTED]

---

**From:** "Lee, Anthony" <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Date:** Friday, June 17, 2022 at 12:52 PM

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]

Thanks for following up, and thank you again for your continued patience as we proceed with the review of your submission. As of right now, there is nothing additional that we currently need from your side. I'm thinking that there won't be anything further beyond administrative requests at this point, although I can't be 100% sure until all the eyes finish going over everything.

Best regards,  
Anthony

**Anthony Lee, PhD, MBA**  
*Team Lead*

**Robotic Assisted Surgery Devices Team**  
**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**  
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**Sent:** Friday, June 17, 2022 3:32 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hello Anthony,

I wanted to check back in with you to stay in communication regarding the status of the review of our file. I am coordinating vacation schedules with several of my engineers and want to make sure we are able to stay responsive to any other questions you might have about our file. Is there anything that I can do from my end to stay aligned with your timing as I work to update my files regarding the review clock and remaining steps?

Thank you, I appreciate it.





**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Tuesday, June 7, 2022 11:00 AM

[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]

[REDACTED]

Best regards,  
Anthony

**Anthony Lee, PhD, MBA**

*Team Lead*

**Robotic Assisted Surgery Devices Team**

**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**

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[REDACTED]

**Sent:** Tuesday, June 7, 2022 1:44 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

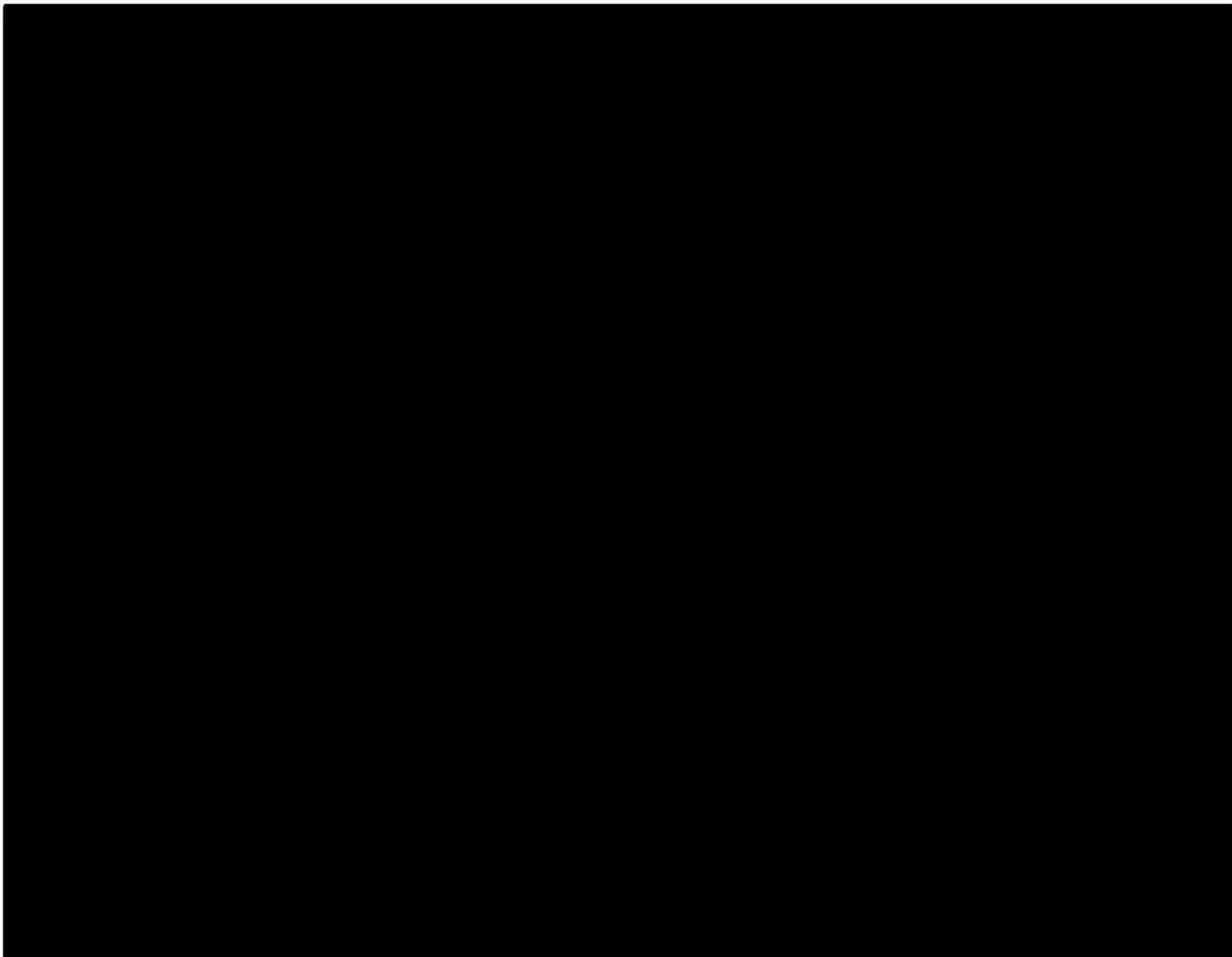
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,

[REDACTED]



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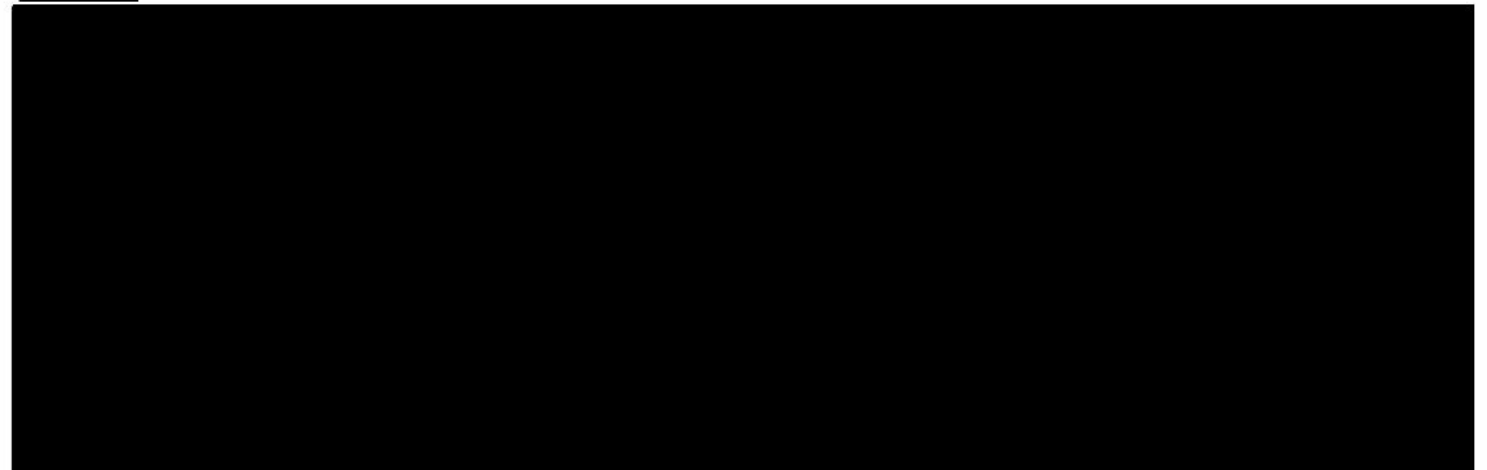
**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Tuesday, June 7, 2022 8:35 AM

[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]



Please let me know if you would like any additional clarification.

Regards,  
Anthony

**Anthony Lee, PhD, MBA**  
Team Lead

**Robotic Assisted Surgery Devices Team**  
**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**  
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**Sent:** Monday, June 6, 2022 5:26 PM

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,

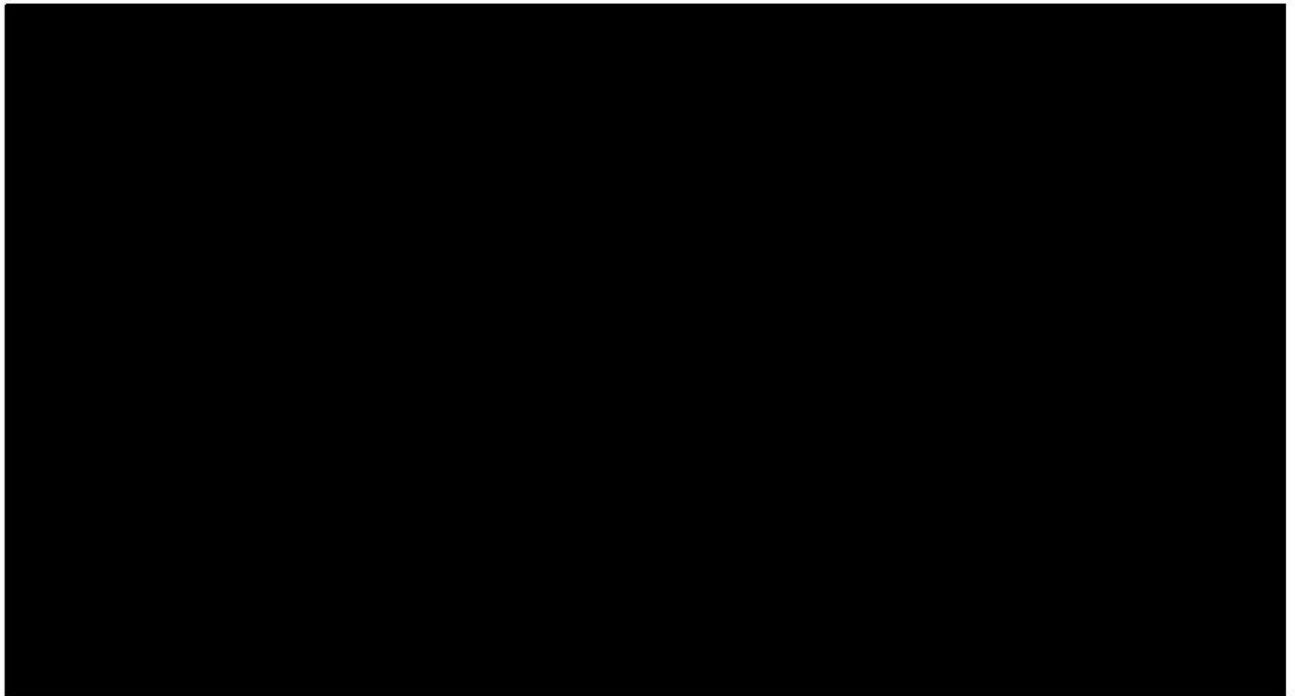
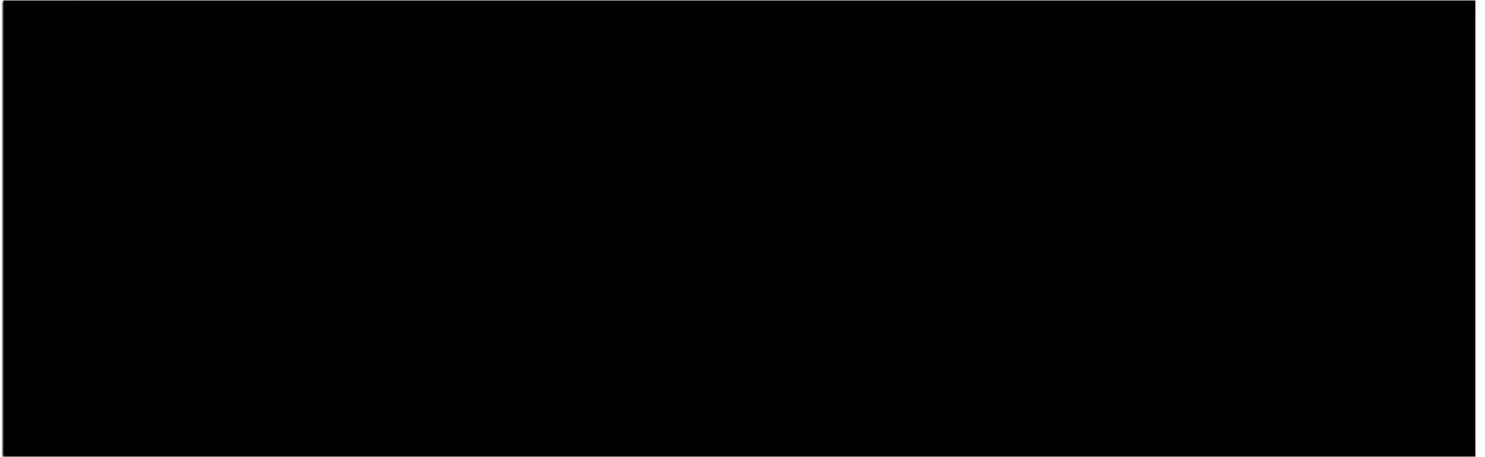
I wanted to check in to confirm you received our response to your latest question. Also, let us know if you need anything else from our end and if possible, please advise on the review status. I appreciate it.

Thank you,

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**Sent:** Wednesday, June 1, 2022 6:05 PM  
**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

[REDACTED]  
**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response





[REDACTED]

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**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Tuesday, May 31, 2022 12:47 PM

[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]

Thank you,  
Anthony

**Anthony Lee, PhD, MBA**

*Team Lead*

**Robotic Assisted Surgery Devices Team**

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[REDACTED]  
**Sent:** Thursday, May 19, 2022 2:44 PM  
**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>  
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,

[REDACTED]

**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>  
**Sent:** Thursday, May 19, 2022 8:33 AM  
**To:** Rafal Chudzik <[rchudzik@alliancehcupartners.com](mailto:rchudzik@alliancehcupartners.com)>  
**Cc:** Rick Ferreira <[rferreira@alliancehcupartners.com](mailto:rferreira@alliancehcupartners.com)>  
**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]

Thank you,  
Anthony

**Anthony Lee, PhD, MBA**  
*Team Lead*

**Robotic Assisted Surgery Devices Team**  
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[REDACTED]  
**Sent:** Monday, May 9, 2022 5:30 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>  
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Thank you Anthony. I will wait to hear back from you.

Thanks,  
[REDACTED]

**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Monday, May 9, 2022 1:54 PM  
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response  
[REDACTED]

Thanks for checking in. There is nothing further needed at this time. The review is still ongoing, and I will let you know if we need additional information.

Thanks,  
Anthony

**Anthony Lee, PhD, MBA**

*Team Lead*

**Robotic Assisted Surgery Devices Team**

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[REDACTED]  
**Sent:** Monday, May 9, 2022 11:16 AM  
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,

I hope you are doing well.

I wanted to check in with you and see if there was any other information that was needed at this time to support your review efforts on our file. Please let me know if anything else is needed.

Thank you,  
[REDACTED]

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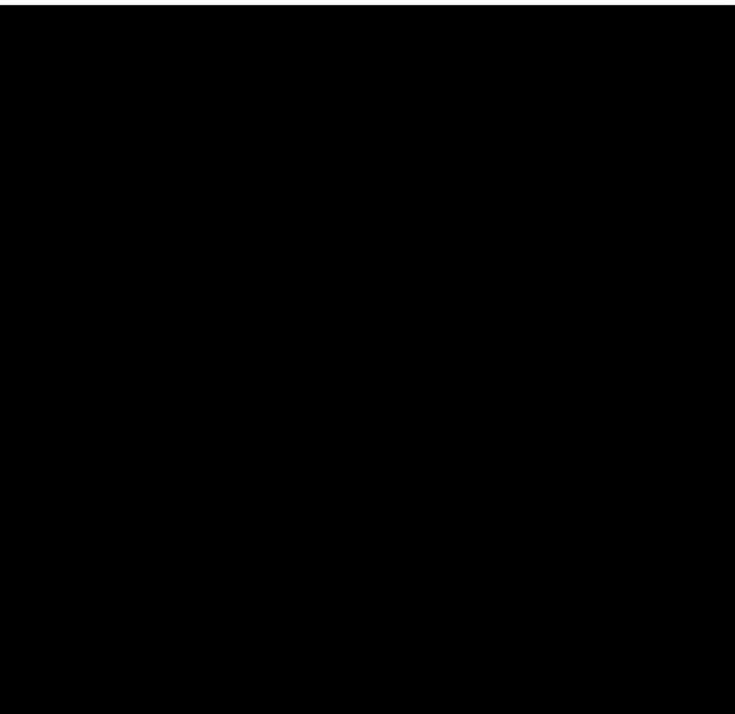
**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Wednesday, April 20, 2022 12:05 PM  
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]





Thank you,  
Anthony

**Anthony Lee, PhD, MBA**  
Team Lead

**Robotic Assisted Surgery Devices Team**  
**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**  
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---

**Sent:** Tuesday, April 19, 2022 4:51 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,

In accordance with FDA 21 CFR Part 803: Medical Device Reporting, Iconocare has established a standardized approach for receiving, recording, and evaluating product complaints under the Medical Device Reporting (MDR) regulations. As part of the Quality System (FDA 21 CFR Part 820: Quality System Regulation) all applicable SOPs will be implemented prior to product commercialization.

In reference to Medical Device Reporting, the list of documents include:

- CAPA SOP
- Medical Device Reporting SOP (including FDA MDR Decision Tree)
- Complaint Handling SOP
- Complaint Form
- Field Correction, Removal and Recall of Product SOP
- Field Complaint Form
- Complaint Investigation SOP

Thank you,

---

**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Tuesday, April 19, 2022 12:29 PM

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

The review team would like to know about your plans for adverse events and MDR reporting. What processes do you have in place for this possibility in the future, assuming your submission receives clearance?

Thank you,  
Anthony

**Anthony Lee, PhD, MBA**

*Team Lead*

**Robotic Assisted Surgery Devices Team**

**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**

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Office: (240) 402-5935

E-mail: [Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)

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[REDACTED]  
**Sent:** Friday, April 15, 2022 1:28 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>; Trumbore, Mark <[Mark.Trumbore@fda.hhs.gov](mailto:Mark.Trumbore@fda.hhs.gov)>  
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,

[REDACTED]

**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Friday, April 15, 2022 8:38 AM

[REDACTED] Trumbore, Mark <[Mark.Trumbore@fda.hhs.gov](mailto:Mark.Trumbore@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]

Thanks,  
Anthony

**Anthony Lee, PhD, MBA**

*Team Lead*

**Robotic Assisted Surgery Devices Team**

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[REDACTED]  
**Sent:** Thursday, April 14, 2022 5:37 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>; Trumbore, Mark <[Mark.Trumbore@fda.hhs.gov](mailto:Mark.Trumbore@fda.hhs.gov)>

[REDACTED]  
**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,

[REDACTED]  
**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Thursday, April 14, 2022 12:57 PM

[REDACTED] Trumbore, Mark <[Mark.Trumbore@fda.hhs.gov](mailto:Mark.Trumbore@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]



[REDACTED]

Thanks,  
Anthony

**Anthony Lee, PhD, MBA**  
Team Lead

**Robotic Assisted Surgery Devices Team**  
**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**  
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E-mail: [Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)

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---

[REDACTED]

**Sent:** Tuesday, April 12, 2022 8:00 AM  
**To:** Trumbore, Mark <[Mark.Trumbore@fda.hhs.gov](mailto:Mark.Trumbore@fda.hhs.gov)>  
**Cc:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>; [REDACTED]  
**Subject:** Re: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Thank you Mark. We appreciate it.

Sent from my iPhone

On Apr 12, 2022, at 4:59 AM, Trumbore, Mark <[Mark.Trumbore@fda.hhs.gov](mailto:Mark.Trumbore@fda.hhs.gov)> wrote:

[REDACTED]

Thank you for your prompt reply. We have no further questions at this time.

Sincerely,

Mark Trumbore-

**Mark W. Trumbore, Ph.D., GWCPM**

*Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team*

DHT4A: Division of General Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4544 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-5436 | Cell: (240) 495-5549 | Fax: (301) 595-7851

[mark.trumbore@fda.hhs.gov](mailto:mark.trumbore@fda.hhs.gov)

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<image023.jpg>

<image024.jpg>

<image025.jpg>

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<image027.jpg>

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<image028.gif>

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**Sent:** Monday, April 11, 2022 11:48 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Trumbore, Mark** <[Mark.Trumbore@fda.hhs.gov](mailto:Mark.Trumbore@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,



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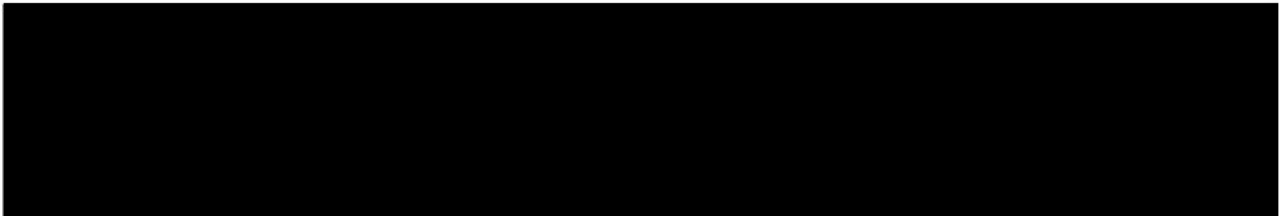
**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Friday, April 8, 2022 12:51 PM



Trumbore, Mark <[Mark.Trumbore@fda.hhs.gov](mailto:Mark.Trumbore@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response



Thanks,  
Anthony

**Anthony Lee, PhD, MBA**  
Team Lead

**Robotic Assisted Surgery Devices Team**  
**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**  
**Office of Product Evaluation and Quality | Center for Devices and Radiological Health**  
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<image034.jpg>

Office: (240) 402-5935  
E-mail: [Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)

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[REDACTED]  
**Sent:** Monday, March 28, 2022 5:49 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>  
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,

I hope you are doing well. We were able to expedite our reports from the vendors and have completed our responses. We plan to have the responses submitted no later than EOD tomorrow, 3/29.

Please let me know if you need anything specific from our team to assist in a smooth process.

Thank you  
[REDACTED]

---

**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Friday, March 4, 2022 12:08 PM  
[REDACTED]  
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response  
[REDACTED]

Good to hear that you may possibly meet the original deadline. Unfortunately it's not policy to review official documents outside the review window. However, if you could send me a heads up when the response is about to head out the door, that would help us prepare and try to ensure that the manpower will be ready when it arrives. Thanks for the update!

Regards,  
Anthony

**Anthony Lee, PhD, MBA**

*Team Lead*

**Robotic Assisted Surgery Devices Team**

**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**

**Office of Product Evaluation and Quality | Center for Devices and Radiological Health**

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<image034.jpg>

Office: (240) 402-5935

E-mail: [Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)

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[REDACTED]  
**Sent:** Friday, March 4, 2022 12:11 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>  
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,

Thank you for that information and for letting me know. That helps – I appreciate it.

[REDACTED]

I appreciate your collaboration – please let us know what we can do to help you with the process.

Best regards,  
[REDACTED]

**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Friday, March 4, 2022 7:49 AM  
[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response  
[REDACTED]

I have an update on the timeline for your submission. I checked with management, and FDA is still allowing extensions on response timelines as a response to the impact of COVID-19. As a result, we have added an additional 180 days to your response window. Your new application response deadline is 9/26/2022. I hope that helps with your opportunity to collect the data needed for your response.

Regards,

Anthony

**Anthony Lee, PhD, MBA**

*Team Lead*

**Robotic Assisted Surgery Devices Team**

**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**

**Office of Product Evaluation and Quality | Center for Devices and Radiological Health**

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Office: (240) 402-5935

E-mail: [Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)

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---

**Sent:** Thursday, February 17, 2022 5:40 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hi Anthony,

I appreciate your quick response.

I will keep you posted on our timing, but its looking like it will be closer to the deadline. I am having a hard time getting commitment from testing labs on outstanding testing reports etc. Labs are significantly delayed and backlogged due to shortages of supplies and labor. We are seeing this across the board. I am working with management and leadership at the vendors to push things along.

I will stay in close communication with you on updates.

Thank you

[REDACTED]

---

**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Thursday, February 17, 2022 2:40 PM

[REDACTED]

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]

Thanks for reaching out. I just checked the system, and your response deadline is 3/30/2022. We look forward to reviewing your response.

Just so we can have a general idea on the timeline, do you think your response will likely be coming in the near term or closer towards the deadline?

Best regards,  
Anthony

**Anthony Lee, PhD, MBA**  
*Team Lead*

**Robotic Assisted Surgery Devices Team**  
**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**  
**Office of Product Evaluation and Quality | Center for Devices and Radiological Health**  
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Office: (240) 402-5935

E-mail: [Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)

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[REDACTED]

---

**Sent:** Thursday, February 17, 2022 4:09 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>



**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hello Anthony,

I hope you are doing well.

I wanted to reconnect with you on our file. We are working on finalizing our responses and I wanted to confirm the final date that the responses are due on the official clock on your end. Can you please let me know when the 180 day clock is due?

Thank you,  
[REDACTED]

---

**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Wednesday, December 1, 2021 1:36 PM

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

[REDACTED]

Thanks for sending this to me in advance. Please make sure to send this to DCC through the official process so it can be reflected in our records. We can discuss the content of the minutes once the amendment has been opened in our system.

Best regards,  
Anthony

**Anthony Lee, PhD, MBA**

*Team Lead*

**Robotic Assisted Surgery Devices Team**

**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**

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Office: (240) 402-5935

E-mail: [Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)



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---

**Sent:** Tuesday, November 30, 2021 6:34 PM

**To:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hello Anthony,

I hope you had a good Thanksgiving.

Thank you again for the call that we had to clarify our remaining points. Attached are the meeting minutes from the call for your review. Please let me know if there are any edits / updates that are needed.

We look forward to the next steps.

---

**From:** Lee, Anthony <[Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)>

**Sent:** Tuesday, October 12, 2021 9:45 AM

**Subject:** RE: [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

I have been asked to take over the review of this submission moving forward. In accordance with the Additional Information letter, the teleconference option within 10 days is to provide additional clarification if any of the feedback could not be understood. Based on the questions provided, you have no clarification questions and are inquiring about whether your planned approach at responding to the deficiencies are acceptable. These types of questions are not appropriate for the 10-day teleconference but can be included with a submission issue q-submission, as stated on page 1 of the letter. Please plan to submit these questions, along with any supporting information, in a Submission Issue Request. The review team can then go over your planned approach and provide a teleconference and/or written feedback upon review of this information.

Thank you,  
Anthony

**Anthony Lee, PhD, MBA**

Team Lead

**Robotic Assisted Surgery Devices Team**

**Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices**

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Office: (240) 402-5935

E-mail: [Anthony.Lee1@fda.hhs.gov](mailto:Anthony.Lee1@fda.hhs.gov)

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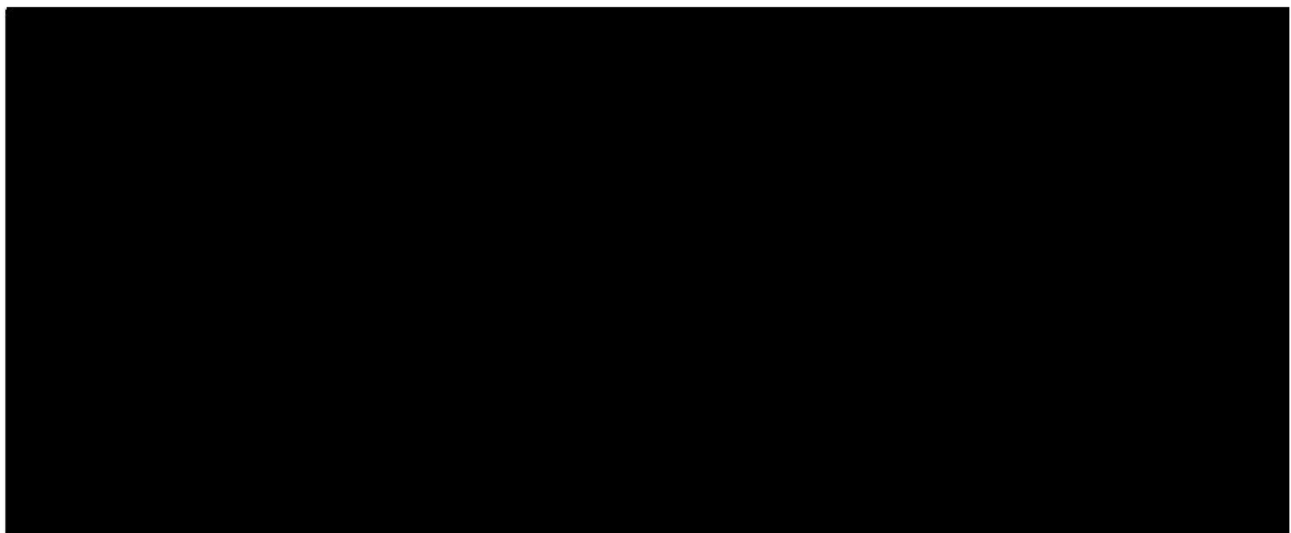
**Sent:** Friday, October 8, 2021 7:07 PM

**To:** Peri, Someswara <[Someswara.Peri@fda.hhs.gov](mailto:Someswara.Peri@fda.hhs.gov)>

**Subject:** [EXTERNAL] RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

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Hello Somesh,





[REDACTED]  
**Sent:** Thursday, October 7, 2021 5:32 PM  
**To:** Peri, Someswara <[Someswara.Peri@fda.hhs.gov](mailto:Someswara.Peri@fda.hhs.gov)>  
[REDACTED]

**Subject:** RE: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

Hello Somesh,

Thank you for your continued efforts on the review of our 510k, K210478. To ensure alignment on the remaining deficiencies, could we please request a teleconference related to K210478/S001?

We have availability early next week at your convenience. I will have the clarification questions sent to you by EOB tomorrow, Friday, 10/8.

I look forward to hearing back from you.

Thank you,  
[REDACTED]

---

[REDACTED]  
**Sent:** Friday, October 1, 2021 11:14 AM  
[REDACTED]

**Subject:** Fwd: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

Sent from my iPhone

Begin forwarded message:

[REDACTED]  
**Date:** October 1, 2021 at 1:11:50 PM CDT  
[REDACTED]  
**Subject:** Fwd: [EXTERNAL]K210478/S001 is on Hold Pending Your Response

FYI

Sent from my iPhone

Begin forwarded message:

**From:** "Someswara Peri [SOMESWARA.PERI]"  
<[someswara.peri@fda.hhs.gov](mailto:someswara.peri@fda.hhs.gov)>  
**Date:** October 1, 2021 at 12:21:57 PM CDT  
[REDACTED]  
**Cc:** "Someswara Peri [SOMESWARA.PERI]"  
<[someswara.peri@fda.hhs.gov](mailto:someswara.peri@fda.hhs.gov)>  
**Subject:** [EXTERNAL]K210478/S001 is on Hold Pending Your Response

October 1, 2021

We have reviewed your submission. Please see attached.



If you have any questions, please contact the lead reviewer assigned to your submission, Someswara Peri.

\*\*\* This is a system-generated email notification \*\*\*